

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9220

Bartle, J.

March 27, 2014

The Estate of Wesley H. Shermantine, Sr. ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart

(continued...)

To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In November, 2009, Barbara Jackson, the representative of the Estate of Wesley H. Shermantine, Sr. ("Mr. Shermantine"), submitted a completed Green Form to the Trust signed by the attesting physician, Patrick S. Coleman, M.D., F.A.C.C., F.S.C.A.I. Based on an echocardiogram dated January 29, 2002, Dr. Coleman attested in Part II of the Green Form that

2. (...continued)

disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

Mr. Shermantine suffered from moderate mitral regurgitation,⁴ moderate aortic regurgitation, an abnormal left atrial dimension, arrhythmias, a reduced ejection fraction in the range of 40% to 49%, and death resulting from a condition caused by VHD or valvular repair/replacement surgery. Based on such findings, the Estate would be entitled to Matrix A-1,⁵ Level V benefits in the amount of \$1,177,381.⁶

4. Dr. Coleman also attested that Mr. Shermantine suffered from New York Heart Association Functional Class III symptoms. This condition is not at issue in this claim.

5. Dr. Coleman originally attested that Mr. Shermantine had aortic root dilatation, the presence of which requires the payment of reduced Matrix Benefits for a claim based on damage to the aortic valve. See Settlement Agreement § IV.B.2.d.(2)(c)i)d). As a result, the Estate originally sought Matrix B-1 benefits for its Level V claim. Subsequently, the Estate submitted a revised Green Form wherein Dr. Coleman changed his representation and, based on an echocardiogram dated January 14, 2000, stated that Mr. Shermantine did not have aortic root dilatation. Given our disposition, we need not resolve this issue.

6. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records," and also had underlying medical conditions sufficient to satisfy the requirements of a Level I or Level II Matrix Claim, Settlement Agreement § IV.B.2.c.(5)(c); Seventh Amendment § I.30.e. A representative claimant is entitled to Level II benefits if the Diet Drug Recipient is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement, see Settlement Agreement § IV.B.2.c.(2)(a), or with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement, see Settlement Agreement

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In the report of Mr. Shermantine's January 29, 2002 echocardiogram, the reviewing cardiologist, John O. Olowoyeye, M.D., F.A.C.C. observed that Mr. Shermantine had "mild mitral regurgitation." Dr. Olowoyeye, however, did not specify a percentage as to the level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Olowoyeye also observed that Mr. Shermantine had "mild aortic insufficiency." Again, however, Dr. Olowoyeye did not specify a percentage as to the level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than 25% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22 and IV.B.2.c.(2)(a).

6. (...continued)

§ IV.B.2.c.(2)(b). The Trust does not contest the attesting physician's finding of a reduced ejection fraction in the range of 40% to 49%, which is one of the complicating factors needed to qualify for Level II claims based on damage to the aortic and mitral valves. Given our determination with respect to Mr. Shermantine's levels of aortic and mitral regurgitation, we need not address whether Mr. Shermantine died as a result of a condition caused by VHD or valvular repair/replacement surgery.

In August, 2010, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for Dr. Coleman's finding that Mr. Shermantine had moderate mitral regurgitation. Specifically, Dr. Wang stated, "Mitral regurgitation was mild because the RLA [sic] and LAA ratio was less than 20%. [Transesophageal echocardiogram] on 7/6/01 showed mild mitral regurgitation." Dr. Wang also concluded that there was no reasonable medical basis for Dr. Coleman's finding that Mr. Shermantine had moderate aortic regurgitation. Dr. Wang explained, "Aortic regurgitation was trace. The JH/LVOT [sic] ratio was less than 10%."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁷ In contest, neither the Estate nor Dr. Coleman addressed the auditing cardiologist's findings as to the Mr. Shermantine's levels of aortic and mitral regurgitation.

The Trust subsequently issued a final post-audit determination, again denying the Estate's claim. The Estate

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On April 13, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8634 (Apr. 13, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on July 14, 2011. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See id. Rule 35.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for its claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate reasserts the arguments it raised in contest. The Estate also argues that it has met all the requisite qualifications for Matrix Benefits, explaining that:

The remaining issues in dispute are really a determination of the degree of valvular regurgitation. Our cardiologist and the auditing cardiologist disagree on the readings. There is no greater explanation that can be given - it simply appears to be a difference of echocardiographic analysis and/or the fact that the doctors seem to be relying on different [echocardiograms] for their findings.

In response, the Trust argues that the Estate is not entitled to Matrix Benefits because there is no reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation and moderate aortic regurgitation and, therefore, the Estate has not established the requisite underlying Level II Matrix Claim necessary for Level V Matrix

Benefits. Specifically, the Trust asserts that the Estate did not refute any aspect of the auditing cardiologist's findings as to mitral or aortic regurgitation.⁹

The Technical Advisor, Dr. Vigilante, reviewed Mr. Shermantine's January 29, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding that it demonstrated moderate aortic regurgitation or moderate mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part:

... There were no color flow images in the left ventricular outflow tract in the parasternal long-axis view. Therefore, the study could not adequately evaluate the presence or absence of aortic regurgitation. An aortic regurgitant jet was not seen in the apical long-axis view although, again, there was poor ultrasound and doppler transmission....

... The left atrial area was calculated at 25.1 cm² in the apical four chamber view. There was an off-axis view of the left atrium in the apical two chamber and the LAA could not be accurately calculated in this view. Color flow images were reviewed in the apical four and two chamber views. Only trace mitral regurgitation was found with the RJA within 1 cm of the mitral annulus noted in the apical four chamber view. Mitral regurgitation was not seen in the apical two chamber view. This study was diagnostic of only trace mitral regurgitation.

9. The Trust also argues that the Estate did not properly contest Dr. Wang's findings with respect to Mr. Shermantine's levels of aortic and mitral valve regurgitation. Given our disposition, we need not determine whether the Estate waived any argument during the contest phase.

Dr. Vigilante also reviewed Mr. Shermantine's January 14, 2000 and July 6, 2001 echocardiograms and similarly concluded that neither of them demonstrated moderate aortic or mitral regurgitation.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. The Seventh Amendment to the Settlement Agreement provides that an eligible representative claimant is entitled to Level V benefits for death resulting from valvular heart disease only when the representative claimant can establish, in addition to the requirements under Section IV.B.2.c(5)(c) of the Settlement Agreement, "that the conditions of the Diet Drug Recipient would have qualified for Matrix Compensation Benefits under Matrix Level I or II as defined in the Settlement Agreement as it existed before the Execution Date, and/or under the requirements of Matrix Level III, IV, or V, as modified and/or clarified in this Section I.B.30." Seventh Amendment § I.30.e. As noted previously, a representative claimant is entitled to Level II benefits if the Diet Drug Recipient is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement, see Settlement Agreement § IV.B.2.c.(2)(a), or with moderate or severe mitral regurgitation and one of five complicating factors delineated in

the Settlement Agreement, see Settlement Agreement

§ IV.B.2.c. (2) (b).¹⁰

As an initial matter, despite suggesting that the different findings of the attesting physician and the auditing cardiologist may be due to reliance on different echocardiograms, the Estate ignores that none of the reports for Mr. Shermantine's echocardiograms states that he had at least moderate aortic or mitral regurgitation. In particular, the report for his January 14, 2000 echocardiogram recites that Mr. Shermantine had mild aortic regurgitation and no mitral regurgitation, while the report of his July 6, 2001 echocardiogram states that Mr. Shermantine had trace aortic regurgitation and "trace to mild" mitral regurgitation. In addition, as noted above, the report for Mr. Shermantine's January 29, 2002 echocardiogram commented that he had only mild aortic and mitral regurgitation.¹¹

Equally significant, the Estate does not adequately rebut the findings of the auditing cardiologist or the Technical Advisor.¹² Both the auditing cardiologist and the Technical

10. The Estate does not allege medical conditions that would qualify for Level I Matrix Benefits.

11. We reject the Estate's argument that Mr. Shermantine's body mass made the echocardiograms difficult to interpret, as the attesting physician, the auditing cardiologist, and the Technical Advisor found the echocardiograms were of sufficient quality to render conclusions as to Mr. Shermantine's medical conditions.

12. Despite an opportunity to do so, the Estate did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Advisor confirmed that none of Mr. Shermantine's echocardiograms revealed the presence of moderate or greater aortic or mitral regurgitation. Specifically, Dr. Wang found that the January 29, 2002 echocardiogram revealed trace aortic regurgitation and, at most, mild mitral regurgitation. Dr. Vigilante concluded that the January 29, 2002 echocardiogram of attestation demonstrated only trace mitral regurgitation and that the presence or absence of aortic regurgitation could not even be determined on the study. As to the July 14, 2000 echocardiogram, Dr. Vigilante determined that "there was no evidence of aortic regurgitation" and "there was no mitral regurgitation seen in color flow mapping of the mitral valve" Finally, Dr. Vigilante concluded that Mr. Shermantine's July 6, 2001 echocardiogram revealed only trace aortic regurgitation and mild mitral regurgitation.

Despite these findings, the Estate does not refute or respond to any of the specific conclusions of the auditing cardiologist or the Technical Advisor. Neither the Estate nor the attesting physician identified any particular error with the findings of the auditing cardiologist and the Technical Advisor. Instead, the Estate seeks to have the Court disregard these findings simply because the attesting physician and auditing cardiologist "disagree on the readings" and there is a mere "difference of echocardiographic analysis." Mere disagreement with the auditing cardiologist or the Technical Advisor, however,

without identifying any specific errors by them, however, is insufficient to meet the Estate's burden of proof.

Finally, to the extent the Estate attempts to rely on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Mr. Shermantine had moderate aortic or mitral regurgitation, such argument is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinions cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded, and the Estate does not adequately dispute, that Mr. Shermantine did not have moderate aortic or mitral regurgitation. To conclude otherwise would allow a representative claimant to receive Matrix Benefits without the required medical conditions. This result would render meaningless the standards established in the Settlement Agreement.¹³ Thus, claimant cannot establish that Mr. Shermantine had moderate aortic or mitral regurgitation, at least one of which is necessary for a Level II Matrix claim.

For the foregoing reasons, we conclude that the Estate has not met its burden in proving that there is a reasonable medical basis for its Level V Matrix claim. Therefore, we will

13. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statements that "[a]n echocardiographer could not reasonably conclude that moderate aortic [or mitral] regurgitation was present on any of these students even taking into account inter-reader variability."

affirm the Trust's denial of the Estate's claim for Level V
Matrix Benefits.